I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on April 9, 2007.

TOWNSEND and TOWNSEND and CREW LLP

By: _____

PATENT
Attorney Docket No.: 14538A-007510US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

BRUCE A. EDGAR *et al.*

Application No.: 10/796,905

Filed: March 8, 2004

For: METHODS FOR IDENTIFYING RHEB EFFECTORS AS LEAD COMPOUNDS FOR DRUG DEVELOPMENT FOR DIABETES AND DISEASES ASSOCIATED WITH ABNORMAL CELL GROWTH

Customer No.: 20350

Confirmation No.: 1659

Examiner: Gerald R. Ewoldt

Art Unit: 1644

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Restriction Requirement dated January 8, 2007, which set forth the following groups of claims:

I. Group I, Claims 2, 5, 6, 8-10, 16, 19, 23, and 24, drawn to a method for identifying a lead compound for diabetes drug development wherein increased Rheb activity is measured, comprising measuring cell size, classified in Class 435, subclass 4+.

II. Claims 3, 5, 6, 8-10, 12, 13, 16, 19, 23, and 24, drawn to a method for identifying a lead compound for diabetes drug development wherein increased Rheb activity is measured, comprising measuring cell viability, classified in Class 435, subclass 4+.

III. Claims 4-6, 8-10, 12, 13, 16, 17, 21, 23, and 24, drawn to a method for identifying a lead compound for diabetes drug development wherein increased Rheb activity is measured, comprising measuring cell glucose uptake or utilization, classified in Class 435, subclass 4+.

IV. Claims 5, 6, 8-11, 16, and 22-24, drawn to a method for identifying a lead compound for diabetes drug development wherein increased Rheb activity is measured, comprising measuring GTPase activity, classified in Class 435, subclass 4+.

V. Claims 5, 6, 14, 15, 16, and 20, drawn to a method for identifying a lead compound for diabetes drug development wherein increased Rheb activity is measured, comprising measuring an enlarged eye phenotype, classified in Class 435, subclass 4+.

VI. Claims 26-29 and 32-34, drawn to a method for identifying a lead compound for drug development for a disease associated with abnormal cell growth wherein decreased Rheb activity is measured, comprising measuring cell size, classified in Class 435, subclass 4+.

VII. Claims 26-28, 30, 32, 33, and 35, drawn to a method for identifying a lead compound for drug development for a disease associated with abnormal cell growth wherein decreased Rheb activity is measured, comprising measuring cell glucose cell uptake or utilization, classified in Class 435, subclass 4+.

VIII. Claims 36-42 drawn to a transgenic non-human animal and a method for producing said animal, classified in Class 800, subclasses 3 and 8.

The Examiner has designated Claims 1, 7, and 18 as linking inventions I-V. This restriction requirement is subject to the non-allowance of linking Claims 1, 7 and 18. Applicant(s) acknowledge that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

The Examiner has designated Claims 25 and 31 as linking inventions VI and VII. This restriction requirement among the linked inventions is subject to the non-allowance of linking Claims 25 and 31. Applicants acknowledge that upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all of the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicants further acknowledge that if any such claim(s) depending from or including all of the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions I-VII are believed to be different methods because the methods employ different reagents acting through different pathways with different endpoints. Therefore, the Examiner believes that the methods are patentably distinct. As such, and because the Examiner believes the inventions have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Although Applicants do not agree with the reasons stated by the Examiner for restriction, Applicants elect to prosecute Group VI, claims 25-29 and 31-34, with traverse. Applicants reserve the right to file a divisional or related application to the subject matter encompassed by any claim of a non-elected group. It is respectfully requested that the Examiner reconsider this restriction in order that Applicants might be allowed a compact and expedited prosecution of the present invention.

Restriction can be required by the Office for certain reasons as set forth in the MPEP under section 800. Such restriction is entirely at the discretion of the Office. Restriction is required so that an undue burden is not placed on the Office in prosecuting the application, so that the statutory fee structure is not subverted, and so that the integrity of the examination and classification system of the Office are not jeopardized. Requirement for restriction is balanced against the right of the Applicants to claim their invention as they require to adequately protect their invention and to provide for a compact and expedited prosecution.

Applicants respectfully submit that the presently claimed invention relates to methods and vectors which together comprise a single inventive concept. Under 35 U.S.C. § 121, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(1) the inventions must be independent or distinct as claimed; and

(2) there must be a serious burden on the examiner if restriction is not required. See MPEP § 803.

Applicants submit that the first of these criteria is not met by the presently claimed invention which relates to the single inventive concept of methods for identifying a lead compound for effecting diseases or conditions related to Rheb activity. The disease or condition can be related to diabetes or abnormal cell growth and the making of transgenic animals that can be used to make transgenic animals useful in these methods. Specifically, the present invention provides methods for identifying a lead compound for diabetes drug development and for a lead compound in abnormal cell growth. Each of these methods measures an increase in Rheb activity for measuring cell size, cell viability or cell glucose uptake. All of the methods are classified in Class 435, subclass 4+. The transgenic animals of Group VIII can be used in any of the above methods. Because these method claims represent a single inventive concept, Applicants believe they properly encompass a single patentable invention.

Second, Applicants believe that because the present claims comprise a single inventive concept, any search of the patent or scientific literature directed to Rheb activity and associated diseases and conditions would be expected to encompass art in the field of the invention as claimed. Thus, prosecution of the invention, as a whole, is not believed to place a burden on the Examiner sufficient to justify restriction.

In view of the above remarks, Applicants respectfully request that the Examiner reconsider the restriction requirement in this application and examine all of the claims as filed as a single invention.

Applicants believe that requirements for responding to the restriction requirement have

been addressed. If a telephone conference would expedite this matter, the Examiner is respectfully encouraged to contact the undersigned accordingly.

Respectfully submitted,

Dated: 9 April 2007

By: Brian W. Poor
Brian W. Poor
Reg. No. 32,928

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, CA 94111
Tel.: (206) 467-9600
Fax: (415) 576-0300
BWP/jms
60966951 v1